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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,101	11/19/2003	Harold L. Atkins	18013-C1	7313
31976	7590	09/30/2005	EXAMINER	
LEWIS J. KREISLER LEGAL DEPARTMENT 930 CLOPPER ROAD GAITHERSBURG, MD 20878			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,101

Applicant(s)

ATKINS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 10-24 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08/04/2005 7-25-05
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 09/22/2005
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION***Response to Amendment***

This is a response to the amendment filed 08/01/05. Specification on page 2 has been amended. Claims 1, 17, 20-22, and 24 have been amended. Claims 2 and 6-9 were canceled. Claims 1, 3-5, 10-24 are pending. Claims 10-16 and 18 were withdrawn from consideration. Claims 1, 3-5, 17, 19-24 are considered and 7-25 before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. An obvious-type double patenting rejection is appropriate where the conflict claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *Berg*, 140 F.3d 1428, 46 USPQ2d

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1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

3. Claims 1-2 and 6-9 are still provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable distinct over claim 35 of copending Application No. 09/664,444 in view of Weber et al. (Crit. Rev. Eukaryot Gene Expr. 2000, Vol. 10, No. 3-4, pp. 281-302) and Rummel et al. (J. Hematotherapy 1994, Vo. 3, pp. 213-218).

4. Claims 1-2, and 6-9 are still provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable distinct over claim 18 of copending Application No. 10, 743, 639 in view of Weber et al. (Crit. Rev. Eukaryot Gene Expr. 2000, Vol. 10, No. 3-4, pp. 281-302) and Rummel et al. (J. Hematotherapy 1994, Vo. 3, pp. 213-218). Because applicants did not raise objection about the rejection, the rejection is maintained.

5. Claims 1-2, and 6-9 are still provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable distinct over claim 18 of copending Application No. 10,743,649 in view of Weber et al. (Crit. Rev. Eukaryot Gene Expr. 2000, Vol. 10, No. 3-4, pp. 281-302) and Rummel et al. (J. Hematotherapy 1994, Vo. 3, pp. 213-218).

6. In the response, applicants did not object about the rejections and stated that they will fill a terminal disclaimer if an allowable subject matter is indicated in the future prosecution. The rejections are therefore, maintained.

7. New Ground Rejection:

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1, 3-5, 17, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (WO 99/18799A1) and Wolff et al. (Human Gene Ther. 1998, Vol. 9, pp. 2277-2284).
10. Claimed invention is directed to an ex vivo method of purging the contaminated neoplastic cells in the mixture of normal hematopoietic cells and neoplastic cells with the oncolytic replication-competent vesicular stomatitis virus. The method further comprises administering a chemotherapeutic agent to the mixture or an interferon to the mixture before, during or after contacting with said virus.
11. Roberts et al. disclose that the replication competent RNS virus VSV is able to kill the tumor cell line in vitro and reduce a neoplasm in the animal implanted tumor model via the oncolytic mechanism exhibited by VSV (See page 8-9, Table 1 on page 22 and claims 1, 116 and 117). Roberts et al. also teach that the method further comprises administration of Interferon or other therapeutic agent (Claims 55-58). Various types of neoplasms disclosed by Roberts et al to be susceptible for the VSV oncolysis include lymphoma and leukemia as well as in the mixture of bone marrow cells (See page 30 and Table 6 on page 38). Roberts et al. do not teach an ex vivo method directed to clean the contaminated cancer cells in the mixture of the autograft stem cells using oncolytic VSV.
12. Wolff et al teach that the specific elimination of contaminated breast cancer cells during autograft cancer therapy is very important. The method comprises to use a recombinant adenovirus carrying prodrug-converting enzyme cytosine deaminase (AdCMV.CD) and 5-fluorocytosine (5-fluorocytosine (5-FC)) (AdCMV.CD/5-FC) specifically kills the tumor cells that efficiently decrease the chance of tumor development after the animals receive the virus treated tumor cells. They suggest that AdCMV-Cd/5-FC may be safely and efficiently applied to purge autografts from breast cancer patients (See 2277, Fig. 5 on 2281 and 1184).
13. Therefore, it would have been obvious for an ordinary person skill in the art in order to increase the therapeutic efficiency and reduce likelihood of cancer remission after autograft cancer therapy with hematopoietic cells possibly contaminated with cancer cells to adapt an ex vivo oncolytic method as suggested by Wolff et al. to purge autografting hematopoietic cells with oncolytic VSV taught by Roberts et al. with a

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highly expected success in view of Roberts et al. 's teaching that VSV can efficiently kill the tumor cells both in vitro and in vivo.

14. As there are no unexpected results have been provided, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER

Baoqun Li
Bao Qun Li

09/23/2005